REMARKS

This Amendment is in response to the Office Action mailed July 8, 2009. This reply is timely filed within the three (3) month time period set forth in the ACTION.

As of the mailing of the current Action, claims 23-25, 27-29, 32-35, 38, 39, 42, 43, 48, 51, 70, and 71 are pending. Applicant has cancelled by this amendment, claims 23-25, 27-29, 32-35, 38, 39, 42, 43, 48, 51, and presents new claims 72-75 for examination. Applicant asserts no new matter is added by these amendments.

Applicant presents herein, claim amendments and a response to the current Action.

Reconsideration is respectfully requested.

Applicant gratefully acknowledges the courtesy of a telephone interview on October 7, 2009 between Examiners Ahmed and Sheikh with applicant's representative David Barman. Applicant has incorporated into this reply, the suggestions kindly offered by the examiners.

I. REJECTIONS UNDER 35 USC 103(a)

Claims 23-25, 27-29, 32-35, 38, 39, 42, 43, 48, 51, 70, and 71 have been rejected under 35 USC 103(a) as being unpatentable over Skinner (US Pat No. 6,210,710), in view of Miller (US Pat Application Publication No 2005/0008690) further in view of Cristoferi et al. (US Pat. No. 5,252,339).

Applicant notes that rejections over prior art were made in the current Office Action. As such, in view of MPEP 707.07 requiring the Action to be complete as to all matters, Applicant's response presented herein addresses the cited references. Applicant acknowledges the MPEP requirement of completeness provides that the currently pending claims are allowable upon a showing that the claimed invention is patentable over these cited references.

Applicant addresses herein the rejection as applied to currently pending claims 70 and 71.

The subject invention, as now claimed, requires, inter alia:

> A composition for timed or retarded release of Glucosamine wherein said composition consists of:
>
> multiple pellets that are formulated from Glucosamine, a shellac solution, and talc that are layered onto inert spheres to form said multiple pellets, said layering forming said multiple pellets having a particle size between 590 µm and 1190 µm;
>
> a hard gelatine capsule enclosing said multiple pellets;
>
> wherein the timed or retarded release composition exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37°C C+/-0.5 degree: after 1 hour about 10% to about 30% of said glucosamine is released; after 4 hours about 50% to about 75% of said glucosamine is released; and after 8 hours about 75% to about 95% of said glucosamine is released. (currently amended claim 70, emphasis added).

The present invention specifically claims a formulation consisting of multiple pellets that are formulated from Glucosamine, a shellac solution, and talc that are layered onto inert spheres to form said multiple pellets. This formulation provides a composition with a specifically defined particle size. The composition imparts a specifically claimed release profile.

Based on the telephone interview of October 7, 2009, Applicant respectfully points out that claims 70 and 71 are disclosed in

the specification, reference being made herein to paragraph numbers in the subject application published as U.S. Patent Application Pub No. 2005/0181047.

The specification states:

> Coating agents, which will act as retarding agents in that they slow the release of the active ingredients, are in a specific embodiment, most specifically polymers such as hydroxypropylmethylcellulo- se or methacrylic polymer, but may also be selected from other agglutinatives and stabilizers such as shellac gum and polyvinyl pyrrolidone (paragraph [0030]).

Shellac is a coating agent as set forth by paragraph [0030]. This is further supported by Exhibit A submitted herewith being a listing from the United States Pharmacopoeia Vol. 25 (2002) which is indicative of the art at the time the invention was made. Pages 2496-2499 list excipients by functional categories. Page 2497 lists shellac under the category “coating agents.”

Coating agents, as are known in the art, are applied as coating layers.

Additionally, shellac, as a coating agent is an agglutinative because the application further defines an agglutinative as

"[an] ingredient that acts at this stage as a permeable agent or layer" (paragraph [0081]). The "layer" is formed of a coating agent as is known in the art.

Shellac, as disclosed in the specification (see paragraphs [0031] and [0081] along with Exhibit A, is, inter alia, an agglutinative, layer-forming material.

The specification further teaches forming a composition using only inert spheres, agglutinative, and lubricant (see paragraphs [0071], [0073] and [0078]). The present invention claims the unexpected result of a functional composition for timed or retarded release of Glucosamine or chondroitin using **only** shellac as the agglutinative layer. In the pharmaceutical art, it is well-known and expected that coating materials require other polymers, binders, plasticizers, fillers, and the like.

The expected need for multiple components of a coating layer is well-known in the art and demonstrated in the cited references of record and in Exhibit B.

Exhibit B, page 932 from Remmington's Science and Practice of Pharmacy, 21st Ed., Lipincott, Williams & Willkins, Baltimore,

MD. (2006), wherein the section entitled "FILM COATING RAW MATERIALS" states: "The main components of any film-forming formulation consist primarily of a polymer, plasticizer, colorant, and solvent (or vehicle).

The agglutinative coating layer of the present invention does not require any of plasticizer, colorant, or solvent.

The present rejection is based on a combination of references. Applicant first discusses the references individually and will follow with discussion of the collective teaching.

Skinner, as cited on page 4 of the current Office Action, discloses a composition that is "beneficial because it provides flexibility in release profiles that are stable and economical for compressed tablets" (Skinner, col. 1, lines 48-56).

Applicant asserts the Skinner reference is deficient on several grounds.

First, Skinner has no disclosure for a delivery system using only an agglutinative. All of the disclosure and examples

disclosed in Skinner require many components to provide the desired release (see Skinner Example 1, col. 6, lines 46-56).

Second, Skinner has no disclosure for shellac. The word "shellac" does not appear anywhere in the Skinner disclosure.

Third, Skinner only teaches tablets, as quoted in the current Office Action, above, and does not teach layered pellets.

Applicant references, at this time, the Rule 132 declaration of record in this case. Dr. Dixit, a scientist with a PhD. in Pharmaceutics and a Registered Patent Agent, positively declared, in paragraph 21:

> Functional coatings, i.e. controlled release, delayed release, sustained release and the like, require attention to different parameters when coating pellets as opposed to coating compressed tablets.

That is to say, Dr. Dixit, being a person having ordinary skill in the art of pharmaceutical formulations understands the differences in parameters that exist and that these parameters and considerations are different when coating layered pellets as opposed to compressed tablets.

Dr. Dixit further declared, paragraph 22:

> Because solid dosage formulation science encompasses a large amount of active ingredients and excipients, suitable percentages for a particular formulation are not attainable through routine or manipulative experimentation as characterized on page 4 of the Office Action.

The declaration of Dr. Dixit is completely congruent with the Examination Guideline published by the USPTO, see "Examination Guidelines for Determining Obviousness Under 35 USC 103 In View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*" See, FR Vol. 72, No. 195, pp. 57527-57335, Oct. 10, 2007 (hereinafter, the "Guideline").

The Guideline states that, in considering obviousness of an invention, even for a combination of known elements, the "operative question is thus 'whether the improvement is more than the predictable use of prior art elements according to their established functions(See "Guideline" at page 57527, col. I, quoting KSR, 550 US at 82 USPQ 2nd at 1391.)

Dr. Dixit clearly declares that "suitable percentages for a particular formulation are not attainable through routine or manipulative experimentation." Thus, there is no "predictable use" as required in the KSR decision. The present invention

requires a specific composition having a specific particle size and imparting a specific release profile. It is a well known fact that a decrease in particle size of separate particles increases surface area. Increased surface area of coated pellets will alter a release profile.

Additionally, applicant asserts that MPEP 2143.01 states:

> Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so.

There is no such teaching, suggestion, or motivation found in any of the cited references alone, or in collective combination for the composition currently claimed because none of the cited references teach using shellac alone without binders, plasticizers and the like. All of the cited references, combined as a single disclosure teach multiple components for formulating controlled release layers.

The Office Action further combines the disclosure of Skinner with Miller. However, the disclosure of Miller fails to cure the deficiency of Skinner. Miller is cited merely to teach some of the specific limitations of pending dependent claims (see

Office Action, page 5). Miller does not have any teaching or suggestion for a formulation to be layered on inert spheres, as currently claimed.

Miller has voluminous listings of materials and no disclosure relating to coating of pellets using shellac. Applicant respectively points out that Miller Example 13, cited on page 4 of the present Office Action simply states:

> The present invention can be utilized with a variety of exipients. Categories of exipients include, but are not limited to, Binders, Disintegrants Fillers (diluents), Lubricants, Glidants (flow enhancers), Compression aids, Colors, Sweeteners, Preservatives, Suspensing/dispersing agents, Film formers/coatings, Flavors, and Printing inks. Still furhter by way of example and not by limitation, the present invention can be utilized with the following exipients: Magnesium Stearate Povidone Lactose Pregelatinized Starch Microcrystalline Hydroxy Propyl Cellulose Methylcellulose Starch (corn) OPA products (coatings Silicon Dioxide & inks) Titanium Dioxide Croscarmellose Stearic Acid Hydroxy Propyl Cellulose Sodium Starch Ethylcellulose Glycolate Calcium Phosphate (dibasic) Gelatin Crospovidone Talc Shellac (and Glaze) Sucrose Calcium Stearate (Miller, paragraph [1548,emphasis added]).

Applicant asserts that in order for a reference to qualify as prior art under 305 USC 103(a), it must teach or suggest the claimed invention. The Miller reference lists known excipients. The Miller reference fails to teach anything about these excipients. The reference simply states "The present invention can be utilized with a variety of excipients." A person having ordinary skill in the art knows these excipients exist. But, to the person having ordinary skill in the art, the list provides no teaching or suggestion on how they are formulated and used.

This is a mere listing of known pharmaceutical excipients. There is no disclosure beyond this list as to formulating with any of the listed excipients. Miller does not teach or suggest anything, least of all, the novel composition of the present invention.

Thus, Skinner alone, as discussed above is deficient for failing to teach or suggest shellac, coated pellets, the particle size and the release profile. The combined disclosure Skinner in view of Miller, whereby Miller merely "lists" shellac with no teaching or suggestion on its' use, still fails to teach or suggest the subject invention as now claimed.

The Office further combines, on page 5 of the instant Office Action, Skinner and Miller with Cristoffi to teach use of a plasticizer. The invention as now claimed, is presented with claim language that the composition consists of shellac, and talc. The currently presented claim excludes plasticizers. Applicant asserts that in view of the present claims exclusion of plasticizers, this reference is no longer relevant.

Applicant reminds the Office of the long-standing principle that the chemical arts are highly unpredictable and require a higher standard for obviousness determinations.

> Although there is a vast amount of knowledge about general relationships in the chemical arts, chemistry is still largely empirical, and there is often great difficulty in predicting precisely how a given compound will behave. In re Dillon 919 F.2d 688, 710 (Fed Cir.,1990).

As stated above, Skinner teaches beneficial tablet formulations and has no disclosure for a composition with a formulation of shellac, coated pellets, the particle size and the release profile as presently claimed. Combination of the teaching of Skinner with the teaching of Miller does not render the subject invention obvious, as set forth above, because chemistry is recognized as being unpredictable and Miller provides a mere list and has no teaching or suggestion for the claimed

formulation layered on inert spheres. The Cristoffi reference, as set forth above, is cited in the Office Action to teach a plasticizer. Thus, in combination Skinner, Miller, and Cristoffi fail to teach or suggest the claimed invention requiring shellac, coated pellets, the particle size and the release profile.

In view of the failure of the cited references to teach, suggest, or provide any type of motivation to modify, in order to achieve the desired and claimed stability, Applicant asserts a rejection under 35 USC 103(a) cannot be properly applied. Applicant respectfully requests reconsideration withdrawal of this rejection.

Based on the Amendments presented herein, Applicant respectfully asserts the application is patentable over the prior art and is now in condition for allowance. If the Examiner believes there are any additional issues that have not been resolved, the Examiner is invited to call the undersigned representative who is attorney of record in this case.

Applicant asserts, no new matter is added by these amendments.

The Commissioner is hereby authorized to charge our Deposit Account No. 19-0734 should any additional fee(s) be required in the filing of this paper to expedite the examination of this application.

Respectfully submitted,

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